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Merck Sharp & Dohme Corp & Anor v Hovid Bhd

B COURT OF APPEAL (PUTRAJAYA) — CIVIL APPEAL NO W-02(IPCV)(W)-1876–10 OF 2016
ABANG ISKANDAR, AHMADI ASNAWI AND MARY LIM JJCA
15 JANUARY 2019

C *Patents — Inventive step — Whether invention obvious — Appellants patented a drug dosing regime and sued respondent for infringing that patent by selling stronger-strength tablets of the same drug — Whether appellants' inventive claim was not patentable under Patents Act 1983 because it did not involve an inventive step — Whether claimed invention obvious to a person having ordinary skill in the area of technology connected to the invention*

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The first appellant ('A1') manufactured a pharmaceutical product known as 'Fosamax' ('the product') that contained alendronate which was a drug used in the treatment of osteoporosis and Paget's disease of bone in humans. The product's dosing regime (ie, the inventive claim of a 70mg weekly dose of alendronate) was granted a Malaysian patent ('the 194 Patent') under the Patents Act 1983 ('the PA'). A1 had licensed the second appellant to exclusively distribute, sell and offer the product for sale in Malaysia. The respondent was granted approval by the National Pharmaceutical Control Bureau to market 'Alendronate' tablets of 70mg strength. The appellants sued the respondent for infringing its patent over the alendronate dosing regime. By way of a counterclaim, the respondent sought a declaration that the 194 Patent was invalid on four grounds, one of which was that the patent lacked inventive step (the expression that was used under European and Malaysian patent law) or that the invention in the patent was 'obvious' (the expression used under USA patent law) and that therefore it was not deserving of protection under the PA. Following a trial, the High Court dismissed three of the four said grounds of invalidation raised by the respondent and ruled that based on the ground that the patent lacked invented step, the 194 Patent and all other claims dependent upon it were invalid. Consequently, the appellants' claim for patent infringement was dismissed. The appellants appealed against the decision while the respondent cross-appealed against the dismissal of its three other 'grounds of invalidation'.

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Held, unanimously dismissing the appeal and the cross-appeal and affirming the High Court's decision:

(1) The trial judge did not err in law or in fact, nor was he plainly wrong, in deciding that the appellants' invention in the 194 Patent did not involve

an inventive step, ie, it was an invention that was 'obvious' to a person having ordinary skill in the area of technology connected to the invention thereby disqualifying it from being patented under the Patents Act 1983. The 194 Patent was not a patentable invention and possessed no legally enforceable patent rights against anyone (see paras 16 & 39–40).

(2) With regard to the relevant prior art, it was in evidence that studies done by REID 1996 and KHAN 1997 had seen that dosages of alendronate as high as 40mg and 80mg had been found to be safe. In view of that, this court agreed with the respondent that it would be obvious to a POSITA of prescribing a dosage of 70mg of alendronate once for duration of seven days as they knew that such a regime would be safe. As such, no inventive step was involved in the creation of the 194 Patent as a method of dosing regime whereby the alendronate was prescribed to be taken 70mg once for a period of seven days. In view of the various prior art that stated that alendronate was generally well tolerated and safe, there was no reason for the court to depart from the trial judge's finding that the 194 Patent lacked inventive step within the meaning envisaged under s 15 of the Patents Act 1983 and that as at the priority date of 15 April 1998, the 194 Patent was not a 'non-obvious' creation in the eyes of a POSITA (see para 28).

[Bahasa Malaysia summary

Perayu pertama ('A1') membuat produk farmaseutikal dikenali sebagai 'Fosamax' ('produk tersebut') yang mengandungi alendronate iaitu dadah yang digunakan untuk merawat osteoporosis dan penyakit Paget untuk tulang manusia. Rejim dos produk (iaitu, tuntutan merekacipta dos mingguan 70mg alendronate) yang diberikan paten Malaysia ('Paten 194') di bawah Akta Paten 1983 ('AP'). A1 telah melesenkan perayu kedua untuk secara eksklusif mengedar, menjual dan menawarkan produk untuk jualan di Malaysia. Responden telah diberikan kelulusan oleh Biro Pengawalan Farmaseutikal Kebangsaan untuk memasarkan tablet 'Alendronate' yangmempunyai kekuatan 70mg. Perayu-perayu tleah menyaman responden-responden kerana melanggar patennya ke atas rejim dos alendronate. Melalui tuntutan balas, responden memohon deklarasi bahawa Paten 194 tidak sah atas empat alasan, salah satunya bahawa paten itu tidak mempunyai langkah merekacipta (ungkapan yang digunakan di bawah undang-undang paten Eropah dan Malaysia) dan bahawa oleh itu ia tidak layak mendapat perlindungan di bawah AP tersebut. Berikutan perbicaraan, Mahkamah Tinggi telah menolak tiga daripada empat alasan ketidaksahan yang ditimbulkan oleh responden dan memutuskan abhawa berdasarkan alasan yang paten tersebut tidak mempunyai langkah merekacipta, Paten 194 dan semua tuntutan lain yang bergantung kepadanya adlaah tidak sah. Akibat itu, tuntutan perayu untuk pelanggaran paten telah ditolak. Perayu-perayu telah merayu terhadap keputusan itu manakala responden telah menuntut balas terhadap penolakan

A tiga 'grounds of invalidation' yang lain.

Diputuskan, sebulat suara menolak rayuan dan rayuan balas dan mengesahkan keputusan Mahkamah Tinggi:

B (1) Hakim perbicaraan tidak terkhilaf dari segi undang-undang atau fakta, mahu pun beliau terkhilaf, dalam memutuskan bahawa cipataan perayu dalam Paten 194 tidak melibatkan langkah ciptaan, iaitu ia adalah satu ciptaan yang 'obvious' kepada seseorang yang mempunyai kemahiran biasa dalam bidang teknologi yang berkait dengan ciptaan sehingga tidak C melayakkannya daripada dipatenkan di bawah Akta Paten 1983. Paten 194 bukan cipataan yang boleh dipatenkan dan tidak memiliki hak paten yang boleh dikuatkuasakan dengan sah terhadap sesiapa (lihat perenggan 16 & 39–40).

(2) Berhubung seni terdahulu yang relevan, ia adalah jelas bahawa kajian D dibuat oleh REID 1996 dan KHAN 1997 telah melihat dos alendronate setinggi 40mg dan 80mg didapati selamat. Berdasarkan itu, mahkamah bersetuju dengan responden bahawa ia adalah jelas kepada POSITA yang preskripsi dos 70mg alendronates adalah sekali untuk tempoh tujuh hari kerana mereka mengetahui rejim tersebut adalah selamat. Oleh itu, tiada E langkah ciptaan yang terlibat dalam ciptaan Paten 194 tersebut kerana cara rejim dos yang mana alendronate dipreskripsi untuk diambil 70mg sekali selama tempoh tujuh hari. Berdasarkan pelbagai seni terdahulu yang menyatakan bahawa alendronate pada amnya boleh diambil dan selamat, maka tiada sebab untuk mahkamah untuk tidak bersetuju F dengan dapatan mahkamah perbicaraan bahawa Paten 194 tidak mempunyai langkah ciptaan dalam maksud yang termaktub di bawah s 15 Akta Paten 1983 dan bahawa sehingga tarikh keutamaan 15 April 1998, Paten 194 bukan ciptaan 'non-obvious' di mata POSITA (lihat perenggan 28).]

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Notes

For cases on whether invention obvious, see 10(1) *Mallal's Digest* (5th Ed, 2017 Reissue) paras 1335–1337.

H **Cases referred to**

Gan Yook Chin (P) & Anor v Lee Ing Chin @ Lee Teck Seng & Ors [2005] 2 MLJ 1, FC (refd)

Henderson v Foxworth Investments Ltd and another [2014] 1 WLR 2600, SC (refd)

I *Onassis and Calogeropoulos v Vergottis* [1968] 2 Lloyd's Rep 403, HL (refd)

SKB Shutters Manufacturing Sdn Bhd v Seng Kong Shutter Industries Sdn Bhd & Anor [2015] 6 MLJ 293; [2015] 9 CLJ 405, FC (refd)

See Hau Global Sdn Bhd v Mah Sing Plastics Industries Sdn Bhd [2018] 1 MLJ 213; [2018] 3 CLJ 359, CA (refd)

Spind Malaysia Sdn Bhd v Justrade Marketing Sdn Bhd & Anor [2017] MLJU 669; [2017] 1 LNS 504, CA (refd)

Legislation referred to

Evidence Act 1950 s 45
Patents Act 1983 ss 15, 27A

Appeal from: Civil Trial No 22IP-72–12 of 2014 (High Court, Kuala Lumpur)

Indran Shanmuganathan (Zaraihan Shaari, Michelle Loi Choi Yoke and Yap Khai Jian with him) (Shearn Delamore & Co) for the appellants.
Cindy Goh Joo Seong (Heidi Lim Ai Yuen and Lim Kuan with her) (Cheang & Ariff) for the respondent.

Abang Iskandar JCA (delivering judgment of the court):

BRIEF FACTS OF THE CASE

[1] Merck Sharp & Dohme Corp ('the first plaintiff') is a company incorporated in the United States of America ('USA') which has been granted a Malaysian Patent No MY-118194-A ('194 Patent') under the Patents Act 1983. Under 194 Patent, the first plaintiff produced a pharmaceutical product of alendronate acid or a pharmaceutically acceptable salt (Alendronate 194) under the trade name 'Fosamax' which had the capability of inhibiting bone resorption in humans.

[2] Merck Sharp & Dohme (M) Sdn Bhd ('the second plaintiff') is a Malaysian company which holds the exclusive license from the first plaintiff to distribute, sell and offer to sell 'Fosamax' products in Malaysia.

[3] The defendant company, Hovid Bhd ('the defendant'), a Malaysian company, has been granted approval by the National Pharmaceutical Control Bureau to market 'Alendronate' 70mg tablets (the defendant's Alendronate 70mg tablets).

[4] In this suit, the plaintiffs claimed that the defendant's import, manufacture, offer for sale, sale and stocking for the purpose of sale or offer for sale of Alendronate 70mg tablets have infringed the 194 Patent ('the plaintiffs' claim'). The defendant, on the other hand, made a counterclaim ('the counterclaim'), for a declaration that the 194 Patent was invalid on a number of grounds, which we will advert to later, in the course of this judgement. Those grounds formed the premise upon which the defendant had mounted its

challenge against the validity of the first plaintiff's claim for patentability of its 194 Patent.

FINDINGS OF HIGH COURT

[5] After a full trial, the judicial commissioner of the High Court ('JC') found that claim 1 of 194 Patent to be invalid on the ground that it was not inventive and as such, all its dependent claims related to 194 Patent were also invalid. Thus, the High Court dismissed the plaintiffs' claim and allowed the defendant's counterclaim in part. The plaintiffs had appealed against the said High Court decision to the Court of Appeal.

[6] The defendant on the other hand, filed a notice of cross-appeal. The defendant claimed that the order that 'the plaintiffs' claim against the defendant is dismissed with costs while the defendant's counterclaim against the plaintiff is allowed' to be varied to 'the plaintiff's claim against the defendant is dismissed with costs while the defendant's counterclaim against the plaintiff is allowed on all grounds of invalidation' and the order that 'the plaintiff's shall pay to the defendant costs in the sum of RM656,853.03 ('awarded costs')' to be varied to 'the plaintiffs shall pay to the defendant costs in the sum of RM1,378,258.19'.

ISSUES RAISED BY THE PLAINTIFFS/APPELLANTS

[7] For the purpose of these grounds of judgment, the plaintiffs hereinafter will be referred to as the appellants and the defendant will be referred to as respondent. In this appeal, the appellants' complaint can be gleaned in the memorandum of appeal. They are briefly as the follows:

(a) the learned JC erred in law and/or fact in failing to hold that the 194 Patent is inventive and a validly granted patent;

(b) the learned JC erred in law and/or in fact in finding claim 1 of 194 Patent to be invalid on the ground that it was not inventive. The learned JC further erred in law and/or in fact when His Lordship went to hold the dependent claims to 194 Patent to be invalid;

(c) the learned JC had erred in law and/or in fact in accepting Professor Ego Seeman ('DW1') and Professor Robert S Langer ('DW2') as relevant skilled persons in the art and relied on their evidence on the selection and manner of reading purported prior arts that led to His Lordship's finding that the 194 Patent was not inventive or was obvious at the relevant priority date;

(d) the learned JC erred in law and/or fact when he accepted and/or preferred the reasoning of DW1 and/or DW2 to Professor Michael Brian Fennerty (PW1) since they are not skilled person(s);

(e) the learned JC erred in fact and/or in law when His Lordship preferred the view of DW1 and DW2 on the purported stock of common general knowledge in the relevant field of art despite them not being persons skilled in the art. In doing so the learned JC gave preference to irrelevant documents/publications over document which formed the stock of common general knowledge at the priority date which resulted in His Lordship finding that the 194 Patent was not inventive or was obvious at the relevant priority date;

(f) the learned JC had erred in law and/or in fact in not having sufficiently considered and/or misinterpreting the views and reasoning of the relevant skilled person (namely PW1) as to what he would regard as common general knowledge as at the relevant priority date of the 194 Patent on 15 April 1998 and the source where he had referred to and/or drew his stock of knowledge from;

(g) the learned JC had erred in law and/or fact in his reading of Lunar News April 1996 and/or Lunar News July 1996 without considering subsequently published documents but before the priority date of 194 Patent thereby resulting in His Lordship's erroneous finding that the 194 Patent was not inventive or was obvious at the relevant priority date; and

(h) the learned JC had erred in law and/or fact when His Lordship failed to give due weight to secondary evidence submitted by the appellants, in the form of documents published after the priority date, as an aid to assess primary evidence submitted by the appellants.

[8] It is worth reiterating here that before the High Court, the challenge that was launched by the respondent was premised upon four grounds. These four grounds could essentially be summed up as follows:

(a) that the 194 Patent was not a patentable invention because it was concerned with a method of treatment of human or animal body by therapy;

(b) that the 194 Patent was neither new nor was it a novelty;

(c) *that the 194 Patent had lacked inventive step*; and

(d) that the 194 Patent had lacked sufficient disclosure.

[9] In the main, as it had come to pass, the learned JC had dismissed three of the four grounds of challenge launched by the respondents and he was only satisfied with the respondent's challenge premised upon the ground that the Patent 194 invention of the appellants had been one that was obvious or that it had lacked the critical element of inventive step. In other words, *the 194 Patent had lacked inventive step*. A ground of challenge premised on this factor has been described as or referred to as one where the impugned product has been

one that is not 'useful' or one that is not 'non-obvious'. It cannot be denied that the learned JC had been greatly assisted in coming to this decision by the evidence led by both parties who had called witnesses who had testified on the prior art pertaining to the 194 Patent, hence impacting on its inventiveness or 'non-obviousness'.

[10] It may be opportune for us to dwell a bit on the concept of 'inventive step' within the ambit and purview of the protection of a patent regime. In essence, inventive step seeks to distinguish if an invention is a new invention or whether it is just an obvious improvement to an already existing invention. Its utility lies in the fact that it goes a long way in ensuring that patents are not accorded to existing inventions. It is not inventive step if it is obvious to a person skilled in the art, having regard to any matter which forms part of the prior art base. The American patent practitioners prefer to regard this essential element as 'non-obviousness'. Thus sometimes, the word 'obvious' features rather prominently in determining whether an invention ought to be patented or otherwise. The European Patent Office ('the EPO') looks at an inventive step as a step going beyond the expectations of technology, instead of just following the next natural step. Whatever term is used to describe it, an invention must exhibit sufficient inventiveness in order to qualify as having fulfilled 'the inventive step' element, before an invention is deserving of being patented. Under the Malaysian legal landscape, a new invention must possess and fulfil the inventive step criterion, before it can be patented under the Patents Act 1983. Section 15 therein defines what is meant by 'inventive step', whereby it is provided that 'such inventive step would not have been obvious to a person having ordinary skill in the art'.

[11] In essence therefore, when an invention may be patentable could be summarised as follows. The subject invention must be useful in the sense that the said invention has a useful purpose. In that sense, it must be operable. In order to evaluate this criterion of patentability, it needed to be shown that the invention under scrutiny has a well-established utility. How may that criterion be determined? That criterion may be met, if a person of ordinary skill in the art would immediately appreciate why the invention was useful based on the characteristics of the invention, by reference for example, to its properties. Also, the utility must be specific, substantial and credible. As regards 'novelty', this criterion refers to the originality of the idea upon which the invention was created. Under this consideration, an invention would not be patentable if it is shown that the invention was known or used by others *before* the patent applicant purportedly invented it. An invention will not be patented if the invention was already patented or described in any printed publication, *before* the patent applicant invented it. That having been said, an invention may be patented if it is shown that it is an improvement to another invention. However, that improvement may be patented only as long as the difference was

not obvious. That brings us to, what is meant by the invention must not be obvious. By this what is meant is that there must be sufficient difference shown in the impugned invention, from what had been used before, such that a person having ordinary skill in the area of technology connected to the invention would not find it obvious to make the change. In other words, the impugned invention did not involve any 'inventive step' for it to be qualified for registration as a patent under the law. Conversely, for an invention to be patentable, it must one that is not obvious to a person having ordinary skill in the area of technology connected to the invention.

[12] At this juncture, suffice for us to state that the learned JC had found that the appellant's product 'Alendronate 194' did not qualify for patenting because it was not shown that it was 'not obvious'. We will reproduce that portion of the learned JC's elaborate finding on this issue in the later part of these grounds of judgment.

[13] The appellants had been aggrieved by this adverse finding by the learned JC and had since filed a notice of appeal in that regard, hence this appeal before us.

[14] At this juncture too, it bears mention that the respondent was not entirely happy with the findings of the learned JC on the other three grounds of challenge and had since filed a cross-appeal pertaining to that issue. We had heard submissions on those complaints by the respondent and at the end of it all, we had unanimously dismissed the respondent's cross-appeal.

[15] In other words, the nett effect of our decision has been that we had effectively affirmed the decision of the learned JC in its entirety, including the matter on costs awarded by the learned JC in favour of the respondent.

[16] We were subsequently informed that the appellants had appealed against our decision that in effect had affirmed the learned JC's finding that the appellants' invention was not, not obvious or that it did not involve any inventive step. In other words, in our respectful view, it was indeed an invention that was obvious to a person having ordinary skill in the area of technology connected to the invention, thereby disqualifying it from being patented.

[17] As such, the learned JC had granted the respondent's counterclaim for invalidation of the 194 Patent because he was of the opinion that the 194 Patent 'lacks inventive step' and as a direct consequence of that, he had also dismissed the appellants' claim for patent *infringement* against the respondent.

[18] It was also made known to us that the respondent had not filed any

notice of appeal against our order that had effectively dismissed their cross-appeal on the three grounds of challenge that we had alluded to in our above paragraphs, prior. We will therefore not dwell on those issues pertaining to the three unsuccessful grounds of challenge by the respondent.

[19] As such, these grounds of judgment are confined to addressing the issue as to whether the learned JC was correct when he found that the invention of the appellants 'Alendronate 194 Patent' was an 'obvious' invention or otherwise one that had lacked any 'inventive step' in its creation, thus was one creation that was not deserving of protection, by way of it being patented under the Patents Act 1983.

[20] The grounds of appeal of the appellants with regard to this issue of the Alendronate 194 was an obvious invention, that had pertained to inventive step or the lack thereof, as found by the learned JC, could be found as articulated in issues Nos 1, 3 and 9 as contained in its memorandum of appeal dated 24 January 2017 ('the MOA') of the appellants. It was the appellants' contention before the learned JC as well as before us that the 194 Patent pertaining to its alendronate was not obvious as at 15 April 1998, the date agreed by both parties as the priority date. The priority date is the date of filing of the first patent application. It is used to establish the novelty or the obviousness of a particular invention relative to other art. Under the Malaysian Patents Act 1983, the relevant provisions pertaining to 'priority date', are contained under s 27A therein.

[21] The challenge by the respondent, had been premised upon the contention that the Alendronate 194 Patent of the appellants' invention was one that was an obvious one. That was one way of saying that the Patent 194 of the appellants did not have the inventive step criterion in the eyes of a person ordinarily skilled in the relevant art or industry in the patent world. That person is a fictional person, and such a person is otherwise also referred to as a *POSITA*. This fictional or notional person is considered to have the normal skills and knowledge in a particular technical field, without being a genius. He or she mainly serves as a reference for determining, or at least evaluating, whether an invention is non-obvious or not (under US patent law), or involves an inventive step or not (under European patent laws). If it would have been obvious for this fictional person to come up with the invention while starting from the prior art, then the particular invention is considered not patentable.

[22] Perhaps it would be helpful here to recall what this action had been about. It had been this. The second appellant, who was the second plaintiff in the court below, was the owner in Malaysian registered patent known as Patent 194, in relation to alendronate dosing regime. Alendronate is a salt, but it has a medical definition assigned to it, like so: 'a hydrated bisphosphonate sodium

salt C4H12NNaO7P2·3H2O used to inhibit bone resorption especially in the treatment of osteoporosis in postmenopausal women and Paget's disease of bone ... called also alendronate sodium' (see *Merriam Webster Dictionary*).

[23] It was submitted by the respondent that the burden of proof would be on the respondent to show that the 194 Patent was not deserving of being patented under in Malaysian Patents Act 1983. Indeed, the respondent had put forth four grounds of challenge before the learned JC in the High Court, and one of those grounds of challenge had been the contention that the 194 Patent exhibited no inventive step, an element so crucial in determining whether to grant an invention a patentable protection under the Malaysian patent law, which is in alignment with both the American as well as the European position in that regard.

[24] The appellants' contrarian argument in response to the challenge had been that the appellants was at the material time, the registered owner of the Patent 194 pertaining to the alendronate dosing issue. By virtue of that fact, it had brought this suit against the respondent for alleged infringement of its patent's right over the alendronate dosing issue.

[25] Both parties had led evidence they thought was necessary to establish their respective case on the balance of probabilities. Witnesses were called and in all three POSITAS were called to testify on the crucial issue of whether there was inventive step involved in the creation or invention of 194 Patent by the appellants. The appellants had called 1 POSITA whereas the respondent had called 2 POSITAS. It would not be remiss on our part to state that the evidence of the POSITAS had played a significant role in determining the outcome of the trial, especially with regards to the question of whether there was inventive step involved in the invention of the Appellants over patent protection that was sought by it. The pertinent question to ask would necessarily be: 'Whether or not the invention surrounding Patent 194 was obvious to a POSITA, or put another way, whether it was just the next natural step in a process in relation to an invention which is already in the public domain in the form of prior art'. If the answer to that postulated question be in the affirmative, then it ought not to be patented.

[26] In a case of this nature, evidence of witnesses who would normally be referred to as experts would usually be led by either or by both parties. Indeed that was done in this case as it had been made clear to us from a perusal of the appeal records. It would be pertinent to lay down here what the apex court had said on this kind of witness by referring to the recent case of *SKB Shutters Manufacturing Sdn Bhd v Seng Kong Shutter Industries Sdn Bhd & Anor* [2015] 6 MLJ 293; [2015] 9 CLJ 405 ('the *SKB Shutters* case') where learned Justice Zulkefli Ahmad Makinudin CJ (Malaya) (as His Lordship then was) had this to

say:

> On the role of expert.
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> [38] On the said questions (5) and (6) posed by the appellant we are of the view the general principles relating to the construction of patent claims and the role to be played by the 'experts' are well-established. The function of the expert is to educate the court in technology and that they come as teachers, as makers of the mantle for the court to don. For that purpose it does not matter if they do not approximate a person skilled in the art (see the case of *Technip France SA's Patent*). As such, clearly the court can construe patent claims without the assistance of a person skilled in the art. Any assistance required is from an expert and he need not approximate a skilled person.
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> [41] We are of the considered view that as the experts who educate the Court on technology, technical terms and common general knowledge do not have to approximate persons skilled in the art, the Court of Appeal was entitled to hold that neither DW3 (the respondent's experts) nor PW1 (the appellant's expert) were *'unimaginative skilled addressees'* and yet make reference to their evidence on technical terms and common general knowledge when assessing if the claims of a patent were obvious.

[27] It was quite clear that the main dispute in the appeal before us had revolved on the evidence of each party's witnesses which could assist the court to determine the inventiveness of the 194 Patent. In this regard, the complaint of the appellants went to the extent as to say that the learned JC was wrong in admitting the evidence emanating from SD1 and SD2 on the ground that they were not POSITAS. Being not POSITAS, their evidence ought not to be admitted *per se.* The premise for this contention by the appellants must be that in law, opinions of persons are not admissible unless the opinions are of persons who are experts. Section 45 of our Evidence Act 1950 is authoritative on that. That having been said, it is the presiding judge who has the final say on the issue with which the expert evidence is concerned. While the expert evidence may be of great assistance to the court, his evidence may not necessarily be conclusive and binding on the presiding judge. It has always been the legal position that, even in the subject matter of expert evidence, the court shall be the ultimate decider, never the expert. This position was reiterated In the recent case of *Spind Malaysia Sdn Bhd v Justrade Marketing Sdn Bhd & Anor* [2017] MLJU 669; [2017] 1 LNS 504 when the Court of Appeal had stated:

> [20] We noted that the learned High Court judge had never in her judgment 'accepting wholesale the opinion of DW3 without considering the opinion offered by PW1 and PW3' as submitted by learned counsel for the appellant. What Her Ladyship stated was she 'will not simply caste aside the evidence of DW3 but will assess his evidence as against the evidence of the plaintiff's expert witness'. We did not find anything wrong with this finding. After all, the court shall be the ultimate decider even in the subject matter of expert evidence. It is not permissible for an expert to substitute his judgment for that of the court. And there is nothing in the law which even faintly suggest that a judge has to surrender his judgment to the

opinion of an expert. See YH Rao & YR Rao on *Expert Evidence (Medical & Non Medical*) 4th Ed 2010 p 94.

[21] In any event, it was not as if the learned High Court judge had ignored totally the evidence of the appellant's experts. In many parts of her grounds of judgment Her Ladyship had considered the evidence of PW1 and PW3. We therefore were of the view that the appellant's contention that the learned High Court judge had erred on this issue was clearly without merits.

[28] Having heard and evaluated the evidence adduced before him, the learned JC had considered the evidence of all the three POSITAS and he had preferred the evidence of DW1 and DW2. In that regard, we agreed with the submission by learned counsel for the respondent that the learned JC was entitled to so act, as it was well within his prerogative. We noted that the learned JC had preferred the evidence of DW1 and DW2 over that of PW1 on account that the former's evidence was backed up by evidence that pertained to the prior art on the subject matter at hand, where the dosage of even 80mg of alendronate per day is already a matter in the public domain, and was considered as being safe. As such, there was no inventive step that was involved in the creation 194 Patent as a method of dosing regime, whereby the alendronate was prescribed to be taken 70mg once for a period of seven days. In regard to the relevant prior art, it was in evidence that studies done by REID 1996 and KHAN 1997 had seen that dosages of alendronate, as high as 40mg and 80mg had been found to be safe. In view of that, we agreed with the submissions by learned counsel for the respondent that it would be obvious to a POSITA of prescribing a dosage of 70mg of alendronate once for a duration of seven days as they knew such a regime would be safe. In fact, PW1 Dr Feherty the POSITA for the appellants agreed that if he wanted to prescribe alendronate once a week, he would multiply seven to the dosage of 10mg daily to make it 70mg once a week. It was the publication of KHAN 1997 that confirmed that a dosage of alendronate as high as 80mg once a day that was key in the learned JC's finding on the relevant prior art, and he was further convinced by the articles as reflected in the LUNAR NEWS. In view of the various prior art that stated that alendronate was generally well tolerated and safe, we found no reason to depart from the finding made by the learned JC that the 194 Patent had lacked inventive step within the meaning as envisaged under s 15 of our Patents Act 1983. We agreed with him too, that in the circumstances, in view of the prevailing prior art as at the priority date namely 15 April 1998, that the 194 Patent would be obvious to a POSITA. Put differently, the 194 Patent was not a non-obvious creation in the eyes of a POSITA.

[29] Having exhaustively considered the relevant evidence before him emanating from the 3 POSITAS, the learned JC came to the following finding:

A I am not satisfied on a balance of probabilities that the expert testimony of Prof Fennerty and the prior art cited by him (alleging that there were serious side effects due to the oral administration of alendronate), could disprove general tolerance of Alendronate as common general knowledge on the priority date. This is because the preponderance of prior art (relied on by Prof Seeman and Prof Langer) supported
B general tolerance of Alendronate as common general knowledge on the priority date. If there were severe side effects associated with the oral administration of alendronate on or before the priority date, there would have been much more prior art (than those cited by Prof Fennerty) to warn medical practitioners and patients of such serious side effects. In fact, doctors would have stopped prescribing alendronate if there were severe side effects arising from its oral administration.
C There might even had been law suits filed against the manufacturers of alendronate. The above decision is consistent with the Canadian decision, at paras 78–97. I must emphasise that the above decision is made for the above reasons without any influence from the Canadian Decision; ...

D **[30]** With respect, we saw no reason to depart from the learned JC's findings on his preference in favour of SD1's and SD2's evidence over that of SP1 (Dr Fennerty) the POSITA witness called by the appellants, for the reasons advanced by him.

E **[31]** As regards the evidence on the question of whether the 194 Patent was an invention created by way of an inventive step on the part of the appellants, we reproduce below the learned JC's findings on the same, like so:

O(1). Does Claim 1 involve inventive step?

F [91] The Plaintiffs had submitted as follows, among others:

(1) on or before the Priority Date, according to Prof Fennerty, a POSITA would know of the following —

(a) oral administration of alendronate to osteoporotic patients would
G cause GI side effects;

(b) GI side effects was dose-related, namely, the higher the dose of alendronate, the greater the GI side effects;

(c) the Major Cause of GI Side Effects —

H (i) was not only because the alendronate failed to pass through the oesophagus but was also due to gastric reflux; and

(ii) was not due to Patience Compliance; and

(d) if a dose higher than then approved 10mg daily of alendronate was
I orally administered to osteoporotic patients, this would cause upper Gl side effects. This was still Prof Fennerty's expert view despite the fact that on the Priority Date, patients with Paget's disease were orally given the then approved 40mg daily of alendronate. This is because, according to Prof. Fennerty, there are differences between osteoporosis and Paget's disease;

(2) on the priority date, the POSITA's 'obvious response' was to 'reduce the dosage of alendronate so as to decrease the quantity and concentration of the toxic active substance to which the esophageal tissue is exposed'. The POSITA would concentrate on proposed solutions to prevent drug-induced esophagitis by —

(a) adjusting the formulation of the tablet, eg by changing its shape, size or coating; or

(b) to reduce the quantity and lower the concentration of alendronate by reducing the unit dosage in the form of dividing the total daily dosage into smaller doses or by sustained release etc;

(3) Prof Fennerty's expert view is that by reading Claims 3, 14, 15 and 20 onto Claim 1, the 'core of the invention' of 194 Patent is the oral administration of 70mg of alendronate in a single weekly dose (70mg weekly dose). On the priority date, the POSITA would not be 'motivated' to arrive at 70mg weekly dose because on the priority date, the POSITA would have considered GI side effects to be dose-related. The 70mg weekly dose was therefore not obvious to a POSITA on the priority date; and

(4) the 70mg weekly dose was a result of an unexpected finding in experiments set up by the first plaintiff to investigate GI side effects following the launch of the 10mg daily tablet of alendronate. The first plaintiff carried out the dog experiments to explore the mechanisms by which bisphosphonate-induced esophagitis was caused. The dog experiments and their results were included in 194 Patent. The findings in dog experiments were supported by subsequent clinical trials and reported in *Schnitzer's Article* (2000).

[92] Based on the above cases as discussed in the above para 90, I adopt the following approach in applying the obviousness test in respect of claim 1:

(1) the POSITA on the priority date should be identified. This has been done in the above paras 61 and 62;

(2) the common general knowledge possessed by the POSITA on the priority date (relevant CGK) should be ascertained. In the above para 69, I have identified the relevant CGK;

(3) the inventive concept of 194 Patent (inventive concept) is determined by way of patent construction. As explained in the above sub-para 66(3), there are four elements of claim 1. The Inventive Concept must be embodied in the four elements of claim 1. Based on the expert testimony of Prof Fennerty as a POSITA, I accept that within the four elements of claim 1, the inventive claim is the 70mg weekly dose;

(4) I find that the following constituted prior art on the priority date (relevant prior art) —

(a) Lunar News (April 1996) (please see the above para 83);

(b) Lunar News (July 1996) (please see the above para 83);

(c) De Groen's Article (3 October 1996);

(d) all the prior art which supports my finding of fact on general tolerance of Alendronate (please see the above sub-para 69(2));

(e) the prior art which substantiates the findings that the major cause of GI side effects is due to the failure of alendronate to pass through the oesophagus and patient compliance [please see the above sub-para 69(3)); and

(f) the prior art which taught about the dosing frequency (which I have found to be part of the relevant CGK in the above sub-para 69(4)).

I do not find the following publications to be part of the Relevant Prior Art —

(i) 834 European Patent Application could not be part of the relevant prior art for the reasons given by Prof Fennerty and elaborated in the above para 87; and

(ii) 624 European Patent Application could not constitute part of the relevant prior art because as explained by Prof Fennerty, 624 European Patent Application concerned 'Treatment of Periodontal Disease with Alendronate';

(5) I shall now ascertain whether there is any difference between the relevant prior art and the inventive concept (70mg weekly dose). I find as a fact the following two differences between the relevant prior art and 70mg weekly dose (two differences) —

(a) the Relevant Prior Art taught regarding the daily dosage of 10mg of alendronate for patients of osteoporosis (10mg Daily Dose); and

(b) 70mg Weekly Dose is clearly different from 10mg Daily Dose in respect of firstly, the dosage, and secondly, the dosing frequency; and

(6) the last inquiry is — viewed without any knowledge of the inventive concept (70mg weekly dose), on the priority date, did the two differences constitute steps which would have been obvious to a POSITA or did the two differences require any degree of invention by the POSITA? This inquiry assumes that the POSITA has no knowledge of 194 Patent.

I find as a fact that on the priority date, without any knowledge of the inventive concept (70mg weekly dose), the two differences constituted steps which would have been obvious to a POSITA and the two differences did not require any degree of invention. This finding is based on the following evidence and reasons:

(a) it was stated at p 31, Lunar News (April, 1996), as follows —

> One of the difficulties with alendronate is its low oral bioavailability. ... *An intermittent treatment program (for example, once per week or one week every three months) with higher oral dosing, needs to be tested.* (Emphasis added.)

As early as Lunar News (April 1996), it would have been obvious to a POSITA that an increase in the dosage of alendronate and a change of the dosing frequency (to once weekly), should be tested;

(b) it was published at p 23, Lunar News (July, 1996), as follows —

The difficulties with oral bisphosphonates may favor their episodic (once/week), or cyclical (one week each month) administration. Even oral alendronate potentially could be given in a *40 or 80mg dose once/week to avoid dosing problems and reduce costs.* (Emphasis added.)

Lunar News (July, 1996) constituted the most convincing Relevant Prior Art whereby the 2 Differences constituted steps which would have been obvious to a POSITA and the 2 Differences did not require any degree of invention by the POSITA.

The Plaintiffs had contended that Lunar News (July, 1996) was published before De Groen's Article (3.10.1996) [which highlighted the severity of GI side effects of alendronate]. As explained in the above sub-paragraph 69(2), I have found as a fact that there was General Tolerance of Alendronate on the Priority Date. As such, I cannot accept De Groen's Article (3.10.1996) regarding the severity of GI side effects of alendronate;

(c) reading together Lunar News (April, 1996) and Lunar News (July, 1996) in a mosaic manner, on the priority date, without any knowledge of the inventive concept (70mg weekly dose), the two differences would have been obvious to a POSITA and the two differences did not require any degree of invention; and

(d) for the above reasons, I prefer the expert views of Prof Seeman and Prof Langer to that of Prof Fennerty.

In view of the above evidence and reasons, I am satisfied that the defendant has succeeded to discharge the legal burden under s 56(2)(a) of the PA to prove on a balance of probabilities that claim 1 lacks an inventive step under ss 11 and 15 of the PA.

[32] In passing, the learned JC had also adverted to the fact, undisputed, that in four other jurisdictions the appellants had also failed to register the 194 Patent as a registered patent, namely in Australia, Canada, the UK and even in the USA. We noted as well that the learned JC had expressly put on record in para 93 of his grounds of judgment the following disclaimer:

I must reiterate that the four foreign decisions are not binding on me. Nor was I influenced by the four foreign decisions in any manner.

[33] Again, we found no reason to disturb the above findings of facts by the learned JC which he had formed as a basis to found his legal finding on the issue of non-obviousness in relation to the 194 Patent.

[34] Although only on the appellants, to wit, that the 194 Patent did not exhibit any inventive step, was enough to knock the said 194 Patent off the Malaysian Register of Patents established under the Patents Act 1983. With that as well, once, the main claim by the appellants has been found to be invalid, it would follow that all dependent claims will be invalid. Authority for that proposition is the Federal Court case of the *SKB Shutters*.

[35] Reverting back to the same decision in the Federal Court case of *SKB Shutters* indeed it has far reaching consequences, even in the context of the present appeal before us. Its consequences on the asppellants' case can only be described as one that is nothing short of dire. We reproduce parts of the *SKB Shutters*' case which are particularly relevant for this court's consideration. As it is related to the issue of 'Claims' the apex court has this to say:

> [19] The claims define the invention in terms of the technical features of the invention (see reg 13(5) of the Regulations). The function of the claims is to define clearly and with precision the monopoly claimed so that others may know the exact boundaries of the area within which they will trespass. Their primary object is to limit and not to extend the monopoly. What is not claimed is disclaimed (see Terrell on the *Law of Patents).*
>
> [20] The first claim is usually the main claim which is made as wide as possible. The subsidiary claims refer to the main claim and include qualifying or explanatory clauses on the various integers of the main claim or optional features. They may also contain independent claims.
>
> *Dependent Claims*
>
> [21] Claims which include all the features of one or more of the other claims are known as dependent claims. They will, if possible at the beginning, contain a reference to the other claim or claims and will then state the additional features claimed (see reg 14 of the Regulations). A claim which is not dependent on another is known as an independent claim.
>
> *Decision*
>
> [24]It is noted that claims (1) and (11) of the appellant's Patent 431 are independent claims. Claims (2) to (10) of the appellant are dependent claims, being dependent on the preceding claims. All are ultimately dependent on claim (1).
>
> [26] As regards the rest of the claims which are dependent claims (claims (2) to (10), we are of the view that having considered claim (11) and claim (1) and found them to be invalid, the Court of Appeal was entitled to then hold that the appellant's Patent 431 was invalid as the rest of the claims, being claims dependent on claim (1), would also fall.
>
> [27] The dependent claims in essence incorporate all the features of the claim upon which it depends but are drafted to only make reference to the claim upon which it depends without expressly setting out all the features of that claim. As such, in the event that the independent claim upon which they depend is invalid, the only way the dependent claim can survive and stand if at all is if the dependent claims are redrafted to incorporate the features of the claim upon which they are dependent

and are made an independent claim. They cannot remain as 'dependent claims' when the claim upon which they depended is invalid. We agree with the contention of the respondents as that was not done in the present case and as it could not be redrafted, the dependent claims must fall (see the case of *E I Du Pont De Nemours & Co v Imperial Chemical Industries Plc & Anor* [2007] FCAFC 63).

[36] In our considered opinion, it could not have been clearer than that. In so far as the matter of claims is concerned, once the main or the principal claim is found by the court to be invalid, all other dependent claims derive no legitimacy on which they could survive. That was what had happened in this case before us. The learned JC had referred to the *SKB Shutters* case as a basis for his decision to rule that all the dependent claims by the appellants were rendered invalid on account of the main claim having been ruled to be invalid for lacking any inventive steps. With respect, we could not say that he was in error by concluding the way he did. He was bound by the decision of the *SKB Shutters* case and as the *SKB Shutters* case emanated from our apex court, we must be bound by it as well vide the principle of stare decisis.

[37] A further consequence of this finding by the learned JC has been that the complaint by the appellants that the respondent was guilty of *infringing* its 194 Patent has been rendered baseless, as it did not have any leg to stand on, as a basis upon which infringement claims may be launched against the respondent.

[38] To our mind, with respect, this proposition must be trite. But if case authority is indeed needed, we would cite the case authority advanced by learned counsel for the respondent in the course of her able submissions. This proposition can find judicial support in the case of *See Hau Global Sdn Bhd v Mah Sing Plastics Industries Sdn Bhd* [2018] 1 MLJ 213; [2018] 3 CLJ 359 ('*See Hau Global* case') where the Court of Appeal had said as follows:

[98] As we have concluded above that MY-055 is invalid, this issue is academic and redundant as the issue of the infringing of MY-055 no longer arises. The issue raised in this appeal is contingent upon the trial court's finding that MY-055 is valid. As we have found otherwise the matters in the appeal no longer arise for consideration. The net result is that the plaintiff is entitled to manufacture and supply wing-shaped pallets with or without protruding ribs in the course of its business. No question of limiting it to any one model arises, in any event.

[39] In short, as Patent 194 is not a patentable invention, no legal rights related to a valid patent could emanate from it, which it could enforce. Such an invention possesses no enforceable patent rights against anybody.

THIS COURT'S FINDINGS AND DECISION

[40] In the circumstances, we were of the view that the learned JC had not erred in law or in fact in coming to his decision pertaining to the issue of the appellants' invention being one that was 'obvious' or that it did not involve an inventive step in the course of its invention of Patent 194. It was for the appellants to convince us that the learned trial judge had committed error or errors of an appealable character, such that we would be justified in invoking our appellate powers in their favour. We were of the considered view that the right party had judgement entered in its favour in the High Court, see the English House of Lords' decision in the case of *Onassis and Calogeropoulos v Vergottis* [1968] 2 Lloyd's Rep 403 ('the *Onassis* case'). On the balance, we were not convinced that the learned JC was plainly wrong when he decided the way he did, in the circumstances and in light of the available evidence as adduced before him. For this, see the case of *Gan Yook Chin (P) & Anor v Lee Ing Chin @ Lee Teck Seng & Ors* [2005] 2 MLJ 1 for the 'plainly wrong' test as a basis upon the appeal court would be justified in setting aside a decision of the trial court. In fact, as relatively recent as in 2014, the English Supreme Court in *Henderson v Foxworth Investments Ltd and another* [2014] 1 WLR 2600 ('the *Henderson*'s case') considered and explained the 'plainly wrong' test as follows:

> 62. Given that the Extra Division correctly identified that an appellate court can interfere where it is satisfied that that criterion was met in the present case, there may be some value in considering the meaning of that phrase. There is a risk that it may be misunderstood. The adverb 'plainly' does not refer to the degree of confidence felt by the appellate court that it would not have reached the same conclusion as the trial judge. It does not matter, with whatever degree of certainty that the appellate court considered that it would have reached a different conclusion. **What matters is whether the decision under appeal is one that no reasonable judge could have reached**. (Bold provided by us for emphasis.)

[41] Applying the principles on the proper invocation of our appellate powers, we were of the considered view that the right party had apparently succeeded in the trial proceedings in the High Court, where the learned JC was not plainly wrong in his decision. We had the benefit of perusing the extensive and exhaustive treatment by the learned JC of the evidence that had been adduced before him in the course of the trial before him. He had subjected those evidence to a fair and no less meticulous judicial appreciation of the entire evidence, both the oral testimonies of the witnesses as well as the numerous documentary evidence inclusive of the educational literature on the prior art pertaining to the alendronate dosage regime. Having done that, we could not say that he was plainly wrong in his conclusions, in fact as well as in law.

[42] Ultimately, having asked ourselves the question as postulated by the

Supreme Court of England in the *Henderson*'s case, we were of the view that the learned JC's decision would be the same as which any reasonable judge could have reached in the given like circumstances. In the words of Lord Pearce in the *Onassis* case: 'But the fact that the right party seems to have succeeded in the court below will naturally make a Court of Appeal extremely reluctant to interfere, and it would only do so in the rarest cases'. We were unanimous in our view that this appeal before us did not fall into that category of cases, described by Lord Pearce as one of the 'rarest cases'.

CONCLUSION

[43] To recapitulate, we found that both the appeal and the cross appeal had no merit. We therefore unanimously dismissed both the appeal and the cross-appeal. We affirmed the learned JC's decision dated 30 August 2016. As to costs here, we ordered each party to bear own costs and that the deposit to be refunded to the appellants.

Appeal and the cross-appeal dismissed unanimously and the High Court's decision affirmed.

Reported by Ashok Kumar